

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 019676, S013

PHARMACOLOGY REVIEW(S)

NDA 19-676/S-013

23 June 1999

Genentech Inc.
460 Point San Bruno Blvd.
South San Francisco, CA 94080-4990

Submission: 29 Jan, 1 Feb 99

PHARMACOLOGY REVIEW OF NDA SUPPLEMENT
Supplement to NDA 19-676 #013

DRUG: Nutropin (somatropin [rDNA origin] for injection)

CATEGORY: Growth hormone.

INDICATION: This submission provides a clinical data supplement to support an additional label claim for improved bone mineral density (BMD) with Nutropin treatment in the adult patient population.

PHARMACOLOGY COMMENTS: There were no preclinical data submitted under supplement S-013 and none is deemed to be needed. Thus, no pharmacology review is necessary for this supplement. There were no labeling changes made to the previously approved preclinical sections of the label.

RECOMMENDATION: AP

cc: NDA 19-676 Orig
HFD-510 Division File
HFD-510 RSteigerwalt
HFD-510 DHertig
HFD-510 CKing

ISI
David H. Hertig
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6/24/99

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**ADMINISTRATIVE DOCUMENTS and
CORRESPONDENCE**